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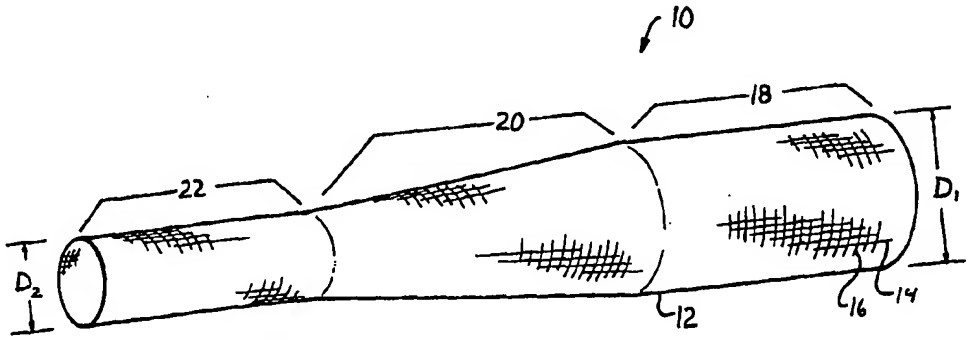

(57) Abstract

The present invention embodies a novel tubular prosthesis (10) and a method for manufacturing a tubular prosthesis. The tubular prosthesis (10) is of seamless woven construction, and has a taper formed along at least a portion of its length (20). The tapered portion (20) of the tubular prosthesis (10) is woven by gradually moving the warp threads (14) closer to each other or further apart. This may be accomplished by progressively moving a tapered reed (56) in relation to the warp threads (14). Each time the warp threads (14) are moved closer to each other or further apart, a predetermined number of weft thread picks (16) are filled into the warp threads (14), and the warp threads (14) are again moved closer together or further apart. The taper-forming process may be applied to both single-lumen tubular prostheses, and tubular prostheses of the bifurcated type.

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TAPERED TUBULAR PROSTHESIS AND METHOD OF MAKING

FIELD OF THE INVENTION

This invention is directed to a woven tapered tubular prosthesis and a method of making a tapered tubular prosthesis by weaving. The tubular prosthesis may be implanted into a patient for various therapeutic purposes..

BACKGROUND OF THE INVENTION

Tubular prostheses are used in a variety of surgical procedures. One particular application for the tubular prosthesis of the present invention is as a vascular graft. Vascular grafts have been used for a number of years in conventional surgical techniques to replace sections of natural blood vessels which have been damaged by trauma or disease, or which have been removed through surgery. Vascular grafts also may be used as bypasses or shunts to bypass an occluded portion of a blood vessel, or to form a new blood passage during vascular reconstruction procedures.

In recent years, it has also become practical to use vascular grafts in an endovascular manner. Endovascular grafts are particularly useful to reinforce damaged areas of blood vessels in which an aneurysm has formed. This is generally done by placing the distal end of a guiding catheter at the location of the aneurysm. A graft is then passed through the guiding catheter and released at the site of the aneurysm. The graft is attached to the walls of the blood vessel by expandable stents mounted on the graft, or by other means. The stents may be of the self-expanding type, or may be expanded using a balloon catheter or similar devices. The guiding catheter is then withdrawn, leaving the graft in place as a reinforcement to the damaged vessel. If the graft is porous, surrounding tissue may grow into the pores of the graft, thereby further strengthening the repair.

Because endovascular grafts must pass through a catheter, it is important that endovascular grafts have as thin a wall as possible. Thus, the wall of an endovascular graft should be much thinner in comparison with conventional non-endovascular grafts. The thin wall enables the graft to be compressed into a small size, thereby enabling the graft to be passed through a smaller diameter catheter. The smaller the diameter of the catheter, the greater the number of sites in the body which the catheter may access, and, accordingly, the greater the number of sites

which are eligible for treatment with a graft. Furthermore, if the catheter diameter is sufficiently small, the catheter can be inserted percutaneously into an artery without cutting of the artery.

One common type of vascular graft prosthesis is the fabric graft. Fabric grafts may be woven, knitted, or braided, and may have smooth or velour surface textures. In the past, knitted and braided grafts were widely accepted over woven grafts because of several perceived advantages. In particular, the perceived advantages of knitted grafts included softness and flexibility. The inherent high porosity and velour surfaces of the grafts were believed to promote healing by the ingrowth of tissue, while softness and flexibility help the graft conform more easily to particular vessel configurations. Braided grafts generally have an even greater porosity than knitted grafts, and are generally substantially less flexible and not as soft as knitted or woven grafts.

It has been found, however, that ingrowth of tissue does not occur to the degree expected in these highly porous grafts, and that the velour surfaces and porosity may only serve to collect tissue, particularly on the inner surface of the graft lumen. In addition, often the porosity of these grafts is so great that hemorrhaging of the graft occurs (i.e., leakage of blood through the graft wall), thereby compromising the effectiveness of the graft, and possibly endangering the patient's life.

Woven grafts have certain advantages over knitted and braided grafts. In particular, woven grafts may be manufactured with thinner walls than knitted or braided grafts. Additionally, woven grafts are generally of higher strength, and can be manufactured with a porosity which is lower than that of knitted and braided grafts. Woven grafts can also be constructed with greater fabric uniformity. Woven grafts generally consist of warp threads (i.e., the threads running in the direction along the major axis of the graft) interwoven with weft threads (also known as pick or fill threads, which are the threads running transversely to the length of the graft). During the weaving process, weft threads are mechanically compacted against adjacent weft threads, leaving only very small pores in the fabric. In certain applications, such as in the case of hemophilia, or when a patient has been given anticoagulants, it is desirable that the graft be virtually impervious to blood leakage.

Grafts for such applications should have very low porosity, and, for fabric grafts, such low porosity is only available in wov n grafts.

When a fabric graft has pores of a size that would normally allow blood to soak through, the pores are often pre-clotted to prevent blood penetration. In pre-clotting, the patient's blood is drawn, and the graft is immersed in the patient's blood for about fifteen minutes to uniformly soak the graft prior to implantation. The blood-drenched graft is then allowed to air dry for a short period of time sufficient for fibrin to build up within the pores of the graft, thereby closing the pores. Pre-clotting can prevent hemorrhaging, while still allowing subsequent tissue ingrowth. However, sometimes pre-clotting is not permissible, as where the patient has been treated with anticoagulants or has bleeding diathesis. Furthermore, even in applications where pre-clotting is used, a low porosity is desirable to ensure the fluid integrity of the graft. In this respect, woven grafts have an advantage over knitted and braided grafts, and, therefore, woven grafts are preferred over knitted and braided grafts.

An alternative to pre-clotting of fabric grafts is the coating of the grafts with a bio-compatible substance such as gelatin, collagen, albumin, or the like. These coatings initially make the graft impervious to blood, but gradually dissipate or otherwise allow tissue ingrowth into the graft material following implantation. The coatings eliminate the need for pre-clotting of the grafts, but the coatings also tend to make the walls of the grafts thicker, stiffer, and more difficult to handle during implantation. As stated above, it is preferable that grafts be as thin-walled as possible for endovascular use. In addition, coated grafts are generally more expensive and difficult to manufacture, and may require special packaging and storage. Accordingly, woven grafts having a low porosity which obviates additional surface treatments are preferred. In addition, it is preferable that the woven grafts be soft and supple for easy handling during implantation.

Conventional woven grafts are formed in a tubular configuration in which the weft filling is a single long thread shuttled continuously through a two-layer array of warp threads, forming a flat tubular body, as described in U.S. Patent No. 3,316,557. The tubular body is then opened to a cylindrical configuration, set, and crimped. However, the prior art woven grafts are formed with a constant lumen diameter throughout the length of the graft. The prior art does not teach a woven

graft having a tapered lumen. Nor does the prior art t ach a method for forming a woven graft having a tapered configuration.

Because human anatomy is often irregular, it is desirable to be able to form a fabric graft in which one end of the graft has a lumen opening which is a different size than the lumen opening at the opposite end of the graft. Such grafts are useful for implantation into vessels having tapered configurations, for connecting vessel openings of differing sizes, or for repairing and bridging an aneurysm in which the vessel lumen on one side of the aneurysm is larger than the vessel lumen at the other side of the aneurysm.

One common use for endovascular grafts is in repairing an aneurysm of the abdominal aorta. The abdominal aorta is prone to aneurysm between the renal and iliac arteries. The wall of the artery at this point becomes unable to withstand arterial pressures, and dilation of the artery in this area may progress until rupture of the artery becomes likely. Conventional surgical procedures for repairing an abdominal aortic aneurysm are highly invasive. A conventional procedure would include an abdominal incision, dissection of the arteries, and interruption of the blood flow to the lower body while a graft is implanted to bypass the aneurysm. This procedure has profound undesirable effects on the respiratory and cardiovascular systems of the patients, and is also expensive and life threatening.

Recently, endovascular treatment of this condition has become possible by endovascular implantation of a graft in the abdominal aorta through a guiding catheter. The catheter is passed percutaneously through an incision in the femoral artery. The distal opening of the catheter is placed at the abdominal aorta, and the vascular graft is passed through the catheter and attached to the walls of the arteries. For such an operation, a bifurcated graft is usually required, as the aneurysm usually occurs at the point where the abdominal aorta branches into the two iliac arteries. Descriptions of typical endovascular abdominal aneurysm repair procedures are set forth in U.S. Patent No. 5,387,235 to Chuter and U.S. Patent No. 5,489,295 to Piplani et al. However, the prior art does not address the problem of matching varying vessel lumen diameters to graft diameter. Furthermore, the prior art does not teach the use of a woven graft having a tapered lumen.

Tapered grafts have been formed in the past by braiding, as shown in U.S. Patent No. 4,441,215 to Kaster. Kaster shows a vascular graft which is braided using multiple filaments to form a tapered lumen. Kaster does not teach or suggest a tapered vascular graft having a woven construction. Additionally, the graft of Kaster is not intended for endovascular use, and, because of its construction, wall thickness, stiffness, and the like, would not be practical for such an application.

Consequently, from an examination of the prior art, it is apparent that a need exists for a woven tubular prosthesis having a tapered lumen. The tubular prosthesis should be constructed with low porosity, when desired, so that pre-clotting is not required. The tubular prosthesis should also be thin-walled so that it may be compacted for endovascular or other non-invasive delivery. The tubular prosthesis and method of the present invention overcome the shortcomings associated with the prior art tubular prostheses, and provide a substantial advance in the art.

SUMMARY OF THE INVENTION

The present invention embodies a novel tubular prosthesis and method for manufacturing a tubular prosthesis. The tubular prosthesis is of woven construction, and has a taper formed along at least a portion of its length. The tubular prosthesis is of low porosity so that it will minimize hemorrhaging, and the tubular prosthesis is thin-walled so that it may be compacted into a small package diameter for use as an endovascular graft. The tapered portion or portions of the tubular prosthesis may be of various lengths, and may be steep or slight. The tapered segments may be incorporated in both single-lumen tubular prostheses, and also in tubular prostheses of the bifurcated type. Furthermore, prostheses may be formed having multiple tapers along their lengths, and the tapered segments of the bifurcated prostheses may be non-uniform, if desired.

Advantageously, the tapered segments of the tubular prosthesis may be formed by controlling the spacing of the warp threads during weaving. The weaving is begun by forming a first-diameter segment of the tubular prosthesis by weaving in a conventional manner. The tapered portion of the tubular prosthesis is then woven by gradually moving the warp threads closer to each other or further apart. This may be accomplished by progressively moving a tapered reed in relation to the

warp threads. Each time the warp threads are moved closer to each other or further apart, a predetermined number of weft thread picks (at least one pick) are filled into the warp threads, and the warp threads are again moved closer together or further apart. The process is repeated until the taper reaches the desired diameter for the second-diameter segment of the tubular prosthesis. The weaving is then continued while holding the reed at a constant position until the second-diameter segment reaches a desired length.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a single-lumen tubular prosthesis of the present invention.

FIG. 2 is a representative view showing how the warp threads of the tubular prosthesis of FIG. 1 are spaced more closely together in the reduced diameter portions.

FIG. 3 is a front elevation view of a loom apparatus for use with the method of the invention.

FIG. 4a is a side cross section view of the loom of FIG. 3, taken along line 4-4, illustrating a process for weaving the tubular prosthesis of the invention.

FIG. 4b shows the loom of FIG. 4a following a pass of the flying shuttle.

FIG. 4c shows the loom of FIG. 4a illustrating the reed in a raised position.

FIG. 5 is a plan view of a first embodiment of a bifurcated tubular prosthesis formed in accordance with the present invention.

FIG. 6 is a plan view of a second embodiment of a bifurcated tubular prosthesis formed in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is directed to a woven tubular prosthesis formed of interwoven warp and weft threads. The tubular prosthesis is formed having at least one tapered segment which transforms the tubular prosthesis lumen smoothly from a first lumen diameter to a second lumen diameter. The taper is formed in the prosthesis by gradually moving the warp threads closer together or further apart during weaving of the tapered portion of the tubular prosthesis.

FIG. 1 shows a tubular prosthesis 10 of the present invention. Tubular prosthesis 10 is a single-lumen tubular prosthesis in the form of an elongate tubular

body 12. Tubular prosthesis 10 preferably may be used as an endovascular graft, but also may be used for other suitable applications, such as a shunt, bypass, or the like. As illustrated in a representative view in FIG. 2, tubular body 12 includes a plurality of warp threads 14 interwoven with a plurality of weft threads 16 woven together in a plain weave construction. Warp threads 14 run parallel to the major axis of tubular body 12, while weft thread picks 16 run perpendicularly to the major axis of tubular body 12. In practice, weft thread picks 16 are comprised of a single thread which is continuously passed back and forth between plural runs of warp threads 14, as will be described in more detail below.

Tubular prosthesis 10 includes a first-diameter segment 18, a tapered segment 20, and a second-diameter segment 22. The relative lengths of segments 18, 20, and 22 may be controlled for various different applications of tubular prosthesis 10. The relative lumen diameters of segments 18, 20, and 22, and the degree of taper of segment 18 also may be controlled for various applications. For example, in FIG. 1, first-diameter segment 18 may be formed with a constant diameter D_1 of 30 mm and a length of 8 cm; second-diameter segment 22 may be formed with a constant diameter D_2 of 17 mm and a length of 17 cm; and tapered segment 20 may be 5 cm in length and taper from first diameter D_1 to second diameter D_2. Of course, these dimensions represent one example, and the relative lengths and diameters of segments 18, 20, and 22 will vary depending on the particular application for which tubular prosthesis 10 is to be used. Using the method of the invention set forth below, tubular prostheses 10 typically might be manufactured having a minimum diameter as small as 8 mm or a maximum diameter as large as 44 mm, although other tubular diameters outside of these ranges may be produced with properly sized equipment and thread.

As illustrated in FIG. 2, warp threads 14 in segment 18 are initially spaced apart from each other a specified distance during the filling of weft thread picks 16. It may be noted that FIG. 2 is only representative of a tubular prosthesis of the present invention, and that the number of warp threads 14 and weft thread picks 16 are actually much greater than what is depicted. For example, a typical tubular prosthesis of the present invention might have as many as 350 warp threads 14 per inch per face (i.e. in a tubular prosthesis 2 inches in circumference, ther would be

700 total warp threads). Similarly, there may typically be as many as 150 weft picks 16 per inch along the length of tubular prosthesis 10. The number of warp threads per inch and picks per inch is limited to a certain extent by the denier of the yarn used, as will be discussed in more detail below.

During formation of tapered segment 20, warp threads 14 are brought gradually closer together, and weft picks 16 are continually filled in and tightly packed in contact with one-another. It should be noted that since weft picks 16 are tightly packed against one another, pores 24 are extremely small, and the prosthesis is of a desirable low porosity. Porosity is generally a function of weave construction, weave density and thread denier. Weave construction and thread denier are usually held constant throughout the construction of a particular tubular prosthesis, although a different denier might be used for weft threads 16 than that used for warp threads 14. However, the weave density may be easily varied along the length of the prosthesis to increase or decrease porosity in a particular segment. In general, weave density is a function of the number of weft picks 16 per inch multiplied by the number of warp threads (or ends) 14 per inch.

The number of weft picks 16 per inch may be varied along the length of the prosthesis. For example, if first diameter segment 18 is formed having 130 picks per inch, and second diameter segment 22 is formed having 100 picks per inch, with tapered segment 20 transitioning between these values, then a tubular prothesis may be formed in which there is little variation between the porosity of first-diameter segment 18, tapered segment 20 and second-diameter segment 22. This is because while warp threads 14 are spaced further apart in segment 18 than they are in segments 20 and 22, weft threads 16 are spaced closer together so that the actual area of the pores does not vary considerably. In addition, even if the number of picks per inch is constant over the length of the prosthesis, because of the tight packing of weft threads 16, the open area of pores 24 does not vary greatly from one end of tubular prosthesis 10 to the other.

Accordingly, tubular prosthesis 10 would usually be formed with a generally constant porosity along its length, although the porosity may be controlled in particular segments by adjusting the number of picks per inch. The water porosity of the prostheses of the present invention generally ranges between 100 and 1200

ml/min/cm^2 @ 120 mm Hg, and would normally not vary more than 25 percent along the length of the prosthesis. In addition, because of the small thread denier, and the large thread density, the wall of the prosthesis is very thin. If a plain weave pattern is used in the construction of prosthesis 10, with a 40 denier thread size, the wall thickness for prosthesis 10 will be approximately 0.004 inch. This thin-walled design enables graft 10 to be compacted into a small diameter, ideal for endovascular applications.

FIGS. 3 and 4a-4c illustrate one form of an apparatus which may be used in the method of manufacturing the tubular prostheses of the present invention. As illustrated in FIG. 3, tubular prosthesis 10 may be manufactured using a loom 50 having a tapered reed 52. Tapered reed 52 is a generally "V"-shaped arrangement of fine wires 56 (known as "dents") which separate warp threads 14 from other warp threads 14 in a manner that is known in the art of weaving. FIG. 3 illustrates tapered reed 52 mounted within a loom frame 54. Tapered reed 52 may be moved up and down within loom frame 54 manually by turning knob 58. For illustration purposes, knob 58 is mounted on a threaded rod 60 which is attached to tapered reed 52. As knob 58 is turned, tapered reed 52 is moved up or down within loom frame 54. Knob 58 may be turned manually by a worker, or may be controlled by a computer or other automatic control device (not shown). Additionally, other methods of moving tapered reed 52 and/or frame 54 include various electro-mechanical, pneumatic, or hydraulic systems (not shown).

FIGS. 4a and 4b illustrate the weaving process in which three runs of warp threads simultaneously pass through tapered reed 52. A first run 62 is located over a second run 64 and a third run 66. Each run 62, 64, 66 consists of a plurality of warp threads spaced apart from the other warp threads within their respective runs by dents 56. There may be, for example, 4, 6, or 8 warp threads per dent 56, dependent upon the total number of warp threads being used in construction of the prosthesis.

During weaving, a shuttle 68 is used to pass a weft thread (not shown) between second run 64 and third run 66, as illustrated in FIG. 4a. Reed 52 is then brought forward to pack the weft thread against the previous weft thread picks. Then, as illustrated in FIG. 4b, second run 64 is lowered, and shuttle 68 passes the

weft thread back in the opposite direction between first run 62 and second run 64, and the weft thr ad is again packed against previous weft thread picks. In this manner first-diameter segment 18 of tubular body 12 is woven in the shape of a flattened tube, as in known in the art.

When it is desired to weave tapered segment 20, reed 52 is raised or lowered a prescribed distance. An additional number of weft picks are then added to tubular body 12. As illustrated in FIG. 4c, tapered reed 52 is progressively raised to weave a tapered tubular prosthesis having a progressively smaller diameter. Once the desired second diameter is reached, additional weft layers may be packed into the warp runs 62, 64, 66, while leaving tapered reed 52 in a constant position. This forms second-diameter segment 22 of tubular prosthesis 10 having a constant prescribed second diameter D_2. It should be noted that the larger diameter segment may be woven first, followed by the tapered segment, and then the smaller diameter segment, or vice versa. In addition, it should be note that an alternative apparatus may be used to weave the tubular prostheses of the present invention. For example, any loom or reed design which enables adjustment of the spacing of the warp threads during the weaving process may be used. Thus, the invention is not limited to weaving with a tapered reed.

FIG. 5 illustrates a bifurcated embodiment 110 of a tubular prosthesis of the present invention. Tubular prosthesis 110 has a bifurcated tubular body 112 having a tubular trunk 130 and a pair of contiguous tubular legs 132. A septum 134 is formed at the junction of legs 132 and trunk 130. The lumen of trunk 130 splits at septum 134 into the lumens of legs 132. Each leg 132 has an initial large-diameter segment 136. Legs 132 then taper along tapered segments 138 to smaller-diameter segments 140.

Tubular prosthesis 110 is particularly useful for endovascular treatment of abdominal aortic aneurysms, as described above in the Background of the Invention. Trunk 130 is placed in the abdominal aorta and legs 132 are placed in the iliac arteries so that prosthesis 110 bridges the aneurysm. The taper of legs 132 enables smaller-diameter segment 140 to match the diameter of the iliac vessels when tubular prosthesis 110 is implanted, while trunk 130 is of a diameter which matches the diameter of the abdominal aorta.

In addition, it should be noted that legs 132 need not be uniform with each other. Thus, under the present invention, a prosthesis may be formed to closely match a particular patient's anatomy. Prospectively, a range of grafts would be provided having a variety of different lumen diameters for each of trunk 103 and legs 132. In the case of a particularly unusual patient, it would be possible to custom-manufacture a prosthesis having specified lumen diameters. Such variety is not available with the grafts of the prior art. It will be apparent that the present invention is a substantial advance over the one-size-fits-all approach of the prior art prostheses.

The construction of bifurcated woven grafts having a main trunk segment and constant-diameter leg segments is known in the art, and is described, for example, in U.S. Patent Nos. 2,924,250 and 4,816,028. In these prior grafts, the trunk and the legs of the bifurcated portion are a constant diameter along their entire lengths. It is not known in the prior art to have a bifurcated woven graft in which the legs 132 are tapered along their lengths, enabling implantation of prostheses which more closely match the anatomy of a particular patient.

Tapered segments 138 of legs 132 are formed in a manner similar to that described above with respect to tapered segment 20 of tubular prosthesis 10 of the first embodiment, although a loom having a pair of tapered reeds may be used in place of a single tapered reed. Following weaving of trunk segment 130, in a conventional manner, large-diameter segments 136 of legs 132 are formed, also in a conventional manner. As legs 132 are woven, tapered segments 138 are formed on legs 132 in the manner described above, by moving warp threads 14 progressively closer together and adjusting weft picks 16 to maintain desired weave density. This may be accomplished using one or more tapered reeds, as described above, or by other suitable means. Septum 134 may be closed by interweaving excess warp threads, as described in the above-mentioned U.S. Patent No. 2,924,250, or by sewing septum 134 following weaving, or by other known methods.

FIG. 6 shows an additional embodiment 210 of a bifurcated tubular prosthesis. Tubular prosthesis 210 includes a tubular body 212 constructed from longitudinal warp threads 14 having a plurality of weft thread picks 16 interwoven therein. Tubular prosthesis 210 includes a tapered trunk 230 and a pair of

contiguous legs 232. It is not known in the prior art to have a woven bifurcated tubular prosthesis having a tapered trunk 230. Trunk 230 may taper inward toward legs 232, as shown in FIG. 6, or may taper outward (not shown), depending upon the anatomy of the patient that prosthesis 210 is intended to be used with.

In treatment of an abdominal aortic aneurysm, tapered trunk 230 is useful for matching the diameters of the arteries, and for smoothing the transition from the larger diameter of the abdominal aorta to the smaller diameters of the iliac arteries when bifurcated tubular prosthesis 210 is implanted. As with tapered legs 132 discussed above, the taper of trunk 230 helps match the size of the tubular prosthesis to the size of the vessel into which the tubular prosthesis is implanted.

Legs 232 of prosthesis 210 are shown in FIG. 6 as having a constant diameter. However, one or both of legs 232 may also be tapered as discussed above with respect to legs 132 of tubular prosthesis 110. Accordingly, a graft may be formed having both a tapered trunk and/or tapered legs. Tapered trunk 230 is produced using the method described above, with warp threads 14 being moved gradually closer together during weaving of the tapered portion of tubular prosthesis 210. Legs 232 and septum 234 are formed using conventional methods, as referenced above, if legs 232 having a constant diameter are desired. If tapered legs are desired, then the legs would be formed as described above with reference to tubular prostheses 10 and 110.

The thread used in forming the tubular prostheses of the present invention is preferably a yarn approved for medical use by the U.S. Food and Drug Administration, such as polyester. A typical size yarn used may be 40 denier/27, which represents 40 grams of yarn per 9000 meters of yarn, and comprises 27 filaments in a single strand of yarn, or 1.48 denier per filament. The selection of 40 d/27 yarn as the standard for the industry is to a certain extent dictated by what is available on the market and approved for medical use. Of course, other suitable yarns of different deniers and materials may be used to construct the tubular prosthesis of the present invention. Accordingly, the invention is not limited to a particular yarn type or denier. In addition, it should be noted that the finer the denier of yarn used, the smaller the pores in the tubular prosthesis will generally be, and, accordingly, the lower the tubular prosthesis porosity. However, if too fine a denier

is used, the threads may break during the weaving process. Thus, typical deniers useful for woven tubular prostheses of the pr_sent invention range between 15 and 150 denier.

In addition, the yarn used may be of the textured type or the flat type. The use of textured yarn will allow the prosthesis to stretch in one or more directions, but also may give the prosthesis a greater wall thickness. As stated above, it is desirable to keep wall thickness at a minimum. Typical wall thickness for the prostheses of the present invention range from 0.003 to 0.010 inch, dependent upon denier of thread and weave pattern.

Following weaving, the tubular prostheses are scoured to remove any oils or other impurities which may have adhered to the threads during the weaving process. This is done by placing the tubular prostheses in a solution of hot water (typically 120° F) and detergent. The prostheses are then rinsed with water to remove the detergent.

The weaving process produces a tubular prosthesis in the shape of a flat tube. However, it is usually desirable to have the tubular prostheses in an open tubular configuration (i.e. with a circular cross section). To attain this, following scouring, the tubular prosthesis is placed on a cylindrical metal mandrel having a tapered shape which matches that of the tubular prosthesis lumen. The tubular prosthesis is then heat-set on the mandrel to form the tubular prosthesis into an open tubular configuration. The tubular prostheses of the present invention are preferably not kinked or corrugated, as is the case with some prior art tubular prostheses, but they could be subjected to such additional treatment if desired.

In addition, it is desirable that the tubular prostheses of the present invention have their ends sealed or otherwise secured to prevent unraveling of the fabric. The sealing may be accomplished by heating or other known means. The tubular prostheses may then be fitted with stents or other devices to facilitate their implantation, and packaged for shipment.

Additional useful features may be incorporated into the tubular prostheses of the present invention. For example, one or more colored warp threads may be used when weaving the tubular prostheses. The colored thread is used by surgeons to indicate kinking or twisting of the tubular prosthesis. In addition, while the inner

and outer surfaces of the tubular prostheses are preferably smooth, the tubular prosthesis outer surfac may be veloured to further encourage ingrowth of tissue following implantation. The velouring process is performed by forming additional loops on the outer surface during filling of the weft threads, as is known in the art of weaving.

From the foregoing, it will be apparent that the present invention sets forth a tubular prosthesis having a woven construction with at least one tapered segment formed therein. The ability to form tapered segments in the prostheses of the present invention enables the prostheses to more closely match the anatomy of a patient than was possible using the prostheses of the prior art. In addition, the prostheses of the present invention are thin walled to facilitate endovascular implantation, and of low porosity. The invention also sets forth a process for manufacturing the a tapered prosthesis of woven construction. Such a prosthesis and method of construction is not known or suggested in the prior art.

Although preferred embodiments have been described herein, it will be recognized that a variety of changes and modifications may be made to the tubular prosthesis and method of the invention without departing from the spirit of the invention, the scope of which is set forth in the following claims.

WHAT IS CLAIMED IS:

1. A woven implantable open-ended tubular prosthesis having a plurality of warp threads interwoven with at least one weft thread, said tubular prosthesis comprising:

a first end having a first diameter, a second end having a second diameter different from said first diameter, and a woven transition segment extending between said first end and said second end,

said tubular prosthesis further including a weaving pattern along said transition segment wherein said weaving pattern has a gradual change in the distance between said warp threads relative to each other to provide a seamless transition between said first diameter of said first end and said second diameter of said second end.

2. The tubular prosthesis of claim1 wherein said first end includes a first segment seamlessly contiguous with said transition segment, said first segment including a seamless woven tubular wall having a constant diameter.

3. The tubular prosthesis of claim 2 wherein said second end includes a second segment seamlessly contiguous with said transition segment, said second segment including a seamless woven tubular wall having a constant diameter.

4. The tubular prosthesis of claim 1 wherein said at least one weft thread is interwoven with said warp threads to comprise a predetermined number of picks per inch, and wherein as said spaces between said warp threads are gradually reduced in said transition segment, the number of picks per inch is gradually reduced so that a generally constant weave density is maintained along the length of said prosthesis.

5. The tubular prosthesis of claim 1 wherein the porosity of said tubular prosthesis is between 100 and 1200 ml/min/cm^2 @ 120 mm Hg.

6. The tubular prosthesis of claim 1 wherein said tubular prosthesis has a wall thickness of less than .010 inch, thereby facilitating the compacting of said tubular prosthesis into a small dimension for enabling implantation of said tubular prosthesis by non-invasive intravascular means.

7. The tubular prosthesis of claim 1 wherein said transition segment is incorporated into a bifurcated tubular prosthesis.

8. A woven tubular prosthesis for implantation into a patient's vasculature, said tubular prosthesis comprising:

a tubular body having a seamless wall woven from a biocompatible thread material, said seamless wall forming at least one lumen,

said tubular body being tapered from a first lumen diameter to a second smaller lumen diameter, wherein said tubular prosthesis has a plurality of warp threads disposed along the direction of the major axis of said tubular body and at least one weft thread interwoven in a plane weave with said warp threads, the distance between said warp threads at said first lumen diameter being greater than the distance between said warp threads at said second lumen diameter for forming a gradual seamless transition along said tubular body between said first lumen diameter and said second lumen diameter.

9. The tubular prosthesis of claim 8 further including a first segment seamlessly contiguous with said tubular body at said first lumen diameter, said first segment including a seamless woven tubular wall having a constant diameter generally equal to said first lumen diameter.

10. The tubular prosthesis of claim 9 further including a second segment seamlessly contiguous with said tubular body at said second diameter, said second segment including a seamless woven tubular wall having a constant diameter generally equal to said second lumen diameter.

11. The tubular prosthesis of claim 8 wherein said at least one weft thread is interwoven with said warp threads to comprise a predetermined number of picks per inch, and wherein as the distance between said warp threads is reduced along said tubular body, the number of picks per inch is gradually reduced so that a generally constant weave density is maintained along the length of said prosthesis.

12. The tubular prosthesis of claim 8 wherein the porosity of said tubular prosthesis is between 100 and 1200 ml/min/cm^2 @ 120 mm Hg.

13. The tubular prosthesis of claim 8 wherein said tubular prosthesis has a wall thickness of less than .010 inch, thereby facilitating the compacting of said

tubular prosthesis into a small dimension for enabling implantation of said tubular prosthesis by non-invasive intravascular means.

14. The tubular prosthesis of claim 8 wherein said tubular body is incorporated into a bifurcated tubular prosthesis.

15. The tubular prosthesis of claim 8 wherein said thread material is between 15 and 150 denier.

16. The tubular prosthesis of claim 11 wherein the wall of said tubular prosthesis has a weave density such that there are between 100 and 150 weft picks per inch.

17. A tubular prosthesis for implantation into a living body, said tubular prosthesis comprising:

an elongate open-ended tubular body, said tubular body having a plurality of warp threads running in the major axial direction of the tubular body, and at least one weft thread interwoven with said warp threads transverse to the major axis of said tubular body, said interwoven warp and weft threads forming a seamless wall,

said tubular body having a first end having a first diameter, a second end having a smaller second diameter, and at least one tapered segment between said first end and said second end, said warp threads at said first end being spaced further apart from each other than said warp threads at said second end, the spaces between said warp threads becoming gradually closer together along said tapered segment in transition from said first diameter to said second diameter; and

wherein said at least one weft thread, by being interwoven with said warp threads, comprises a predetermined number of picks per inch, such that as the distance between said warp threads is reduced along said tubular body, the number of picks per inch is gradually reduced so that a generally constant weave density is maintained along the length of said prosthesis.

18. The tubular prosthesis of claim 17 wherein the wall of said tubular prosthesis has a weave density such that there are between 100 and 150 weft picks per inch.

19. The tubular prosthesis of claim 17 wherein the porosity of said tubular prosthesis is between 100 and 1200 ml/min/cm^2 @ 120 mm Hg.

20. The tubular prosthesis of claim 17 wherein said tubular prosthesis has a wall thickness of less than .010 inch, thereby facilitating the compacting of said tubular prosthesis into a small dimension for enabling implantation of said tubular prosthesis by non-invasive intravascular means.

21. The tubular prosthesis of claim 17 wherein said tubular body is incorporated into a bifurcated tubular prosthesis.

22. A woven implantable tubular prosthesis having a seamless wall, said tubular prosthesis comprising:

a first tubular segment, said first segment having a first diameter;

a second tubular segment having a second diameter smaller than said first segment;

a tapered tubular segment having a first end and a second end, said tapered segment being seamlessly contiguous with said first segment on said first end, and seamlessly contiguous with said second segment on said second end, and extending between said second segment and said first segment;

a plurality of warp threads disposed generally parallel to the longitudinal axis of said tubular prosthesis and at least one weft thread interwoven with said warp threads in a plurality of filling picks for forming said seamless wall of said tubular prosthesis, wherein said warp threads at said first tubular segment are spaced apart from each other a first distance and said warp threads at said second tubular segment are spaced apart from each other a second distance less than said first distance, and said warp threads gradually transition from said first distance to said second distance along the extent of said tapered tubular segment, with the number of warp threads remaining constant along the length of said tapered segment.

23. The tubular prosthesis of claim 22 wherein said at least one weft thread, by being interwoven with said warp threads, comprises a predetermined number of picks per inch, and wherein as the distance between said warp threads is reduced along said tapered segment, the number of picks per inch is gradually

reduced so that a generally constant weave density is maintained along the length of said prosthesis.

24. The tubular prosthesis of claim 22 wherein the wall of said tubular prosthesis has a weave density such that there are between 100 and 150 weft picks per inch.

25. The tubular prosthesis of claim 22 wherein the porosity of said tubular prosthesis is between 100 and 1200 ml/min/cm^2 @ 120 mm Hg.

26. The tubular prosthesis of claim 22 wherein said tubular prosthesis has a wall thickness of less than .010 inch, thereby facilitating the compacting of said tubular prosthesis into a small dimension for enabling implantation of said tubular prosthesis by non-invasive intravascular means.

27. The tubular prosthesis of claim 22 wherein said first segment, said second segment, and said tapered segment are incorporated into a bifurcated tubular prosthesis.

28. A method for forming a woven tapered tubular prosthesis, said method comprising:

providing a plurality of warp threads spaced apart from each other by a reed;

interweaving at least one weft thread with said warp threads for forming a seamless tubular body;

adjusting said reed relative to said warp threads so that said warp threads are moved closer to each other or further from each other by said reed; and

further interweaving said at least one weft thread with said warp threads so that at least a segment of said tubular body is tapered.

29. The method of claim 28 further including the step of placing said tubular prosthesis upon a mandrel following weaving and heating said tubular prosthesis to assume an open tapered tubular shape.

30. The method of claim 28 further including the step of scouring said tubular prosthesis following weaving to remove oil and contaminants therefrom.

31. The method of claim 28 wherein said tubular prosthesis is woven so as to form a single lumen tapered tubular prosthesis.

32. The method of claim 28 wh rein said tubular prosthesis is woven in a bifurcated configuration having a trunk and a pair of contiguous legs, said legs including tapered segments.

33. The method of claim 28 wherein said tubular prosthesis is woven into a bifurcated configuration having a trunk and a pair of contiguous legs, said trunk including a tapered segment.

34. The method of claim 28 wherein said tubular prosthesis is woven into a bifurcated configuration having a trunk and a pair of contiguous legs, with at least one tapered body segment therein, with a septum located at the juncture of said legs and said trunk, said septum being of woven construction.

35. A method of making a woven tubular prosthesis having at least one tapered segment, said method comprising:

providing a first run of a plurality of warp threads within a loom;

providing a second run of a plurality of warp threads below said first run within said loom;

providing a third run of a plurality of warp threads below said first run and said second run within said loom, some of said warp threads in each said run being laterally spaced from others of said warp threads in the same run by a plurality of dents;

interweaving a weft thread with said warp threads for forming a tubular body, whereby a tapered segment is formed by progressively moving said dents relative to said warp threads to affect the lateral spacing of said warp threads from others of said warp threads in each said run during interweaving of said weft thread.

36. The method of claim 35 further including the step of placing said tubular prosthesis upon a mandrel following weaving and heating said tubular prosthesis to assume an open tapered tubular shape.

37. The method of claim 35 wherein said tubular prosthesis is woven so as to form a single lumen tapered tubular prosthesis.

38. The method of claim 35 wherein said tubular prosthesis is woven in a bifurcated configuration having a trunk and a pair of contiguous legs, said legs including tapered segments.

39. The method of claim 35 wherein said tubular prosthesis is woven into a bifurcated configuration having a trunk and a pair of contiguous l gs, said trunk including a tapered segment.

40. The method of claim 35 wherein said tubular prosthesis is woven into a bifurcated configuration having a trunk and a pair of contiguous legs, with at least one tapered body segment therein, with a septum located at the juncture of said legs and said trunk, said septum being of woven construction.

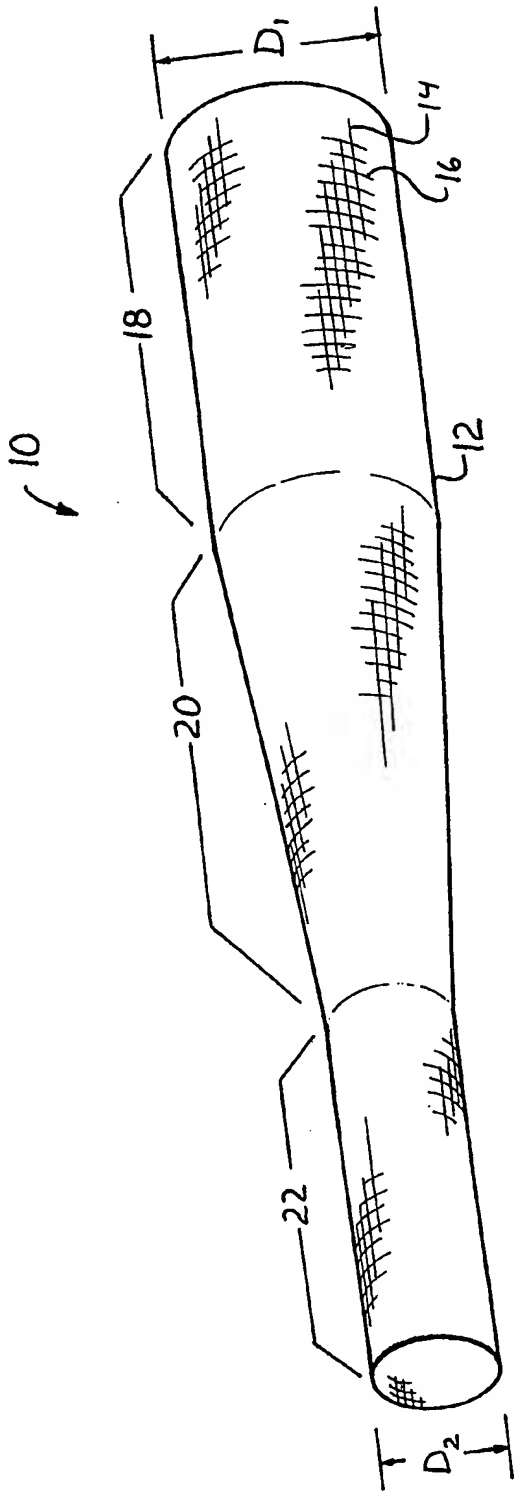

FIG. 1

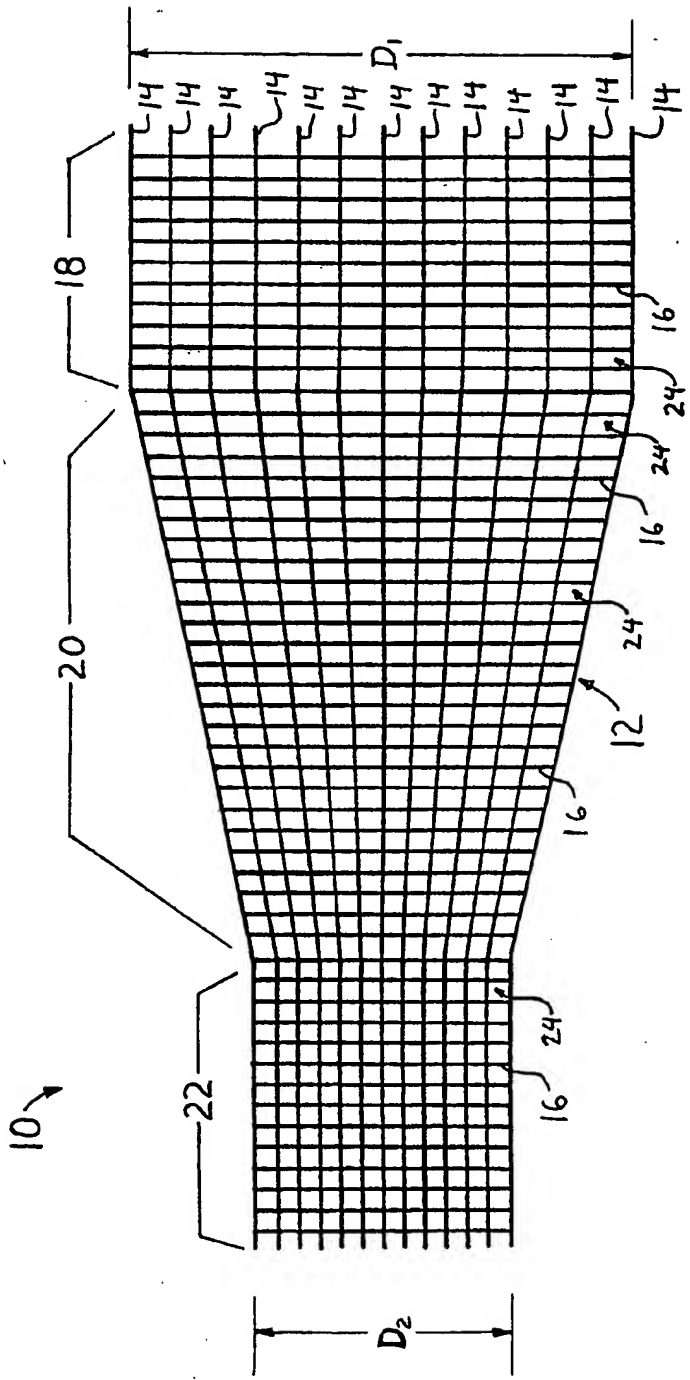

FIG. 2

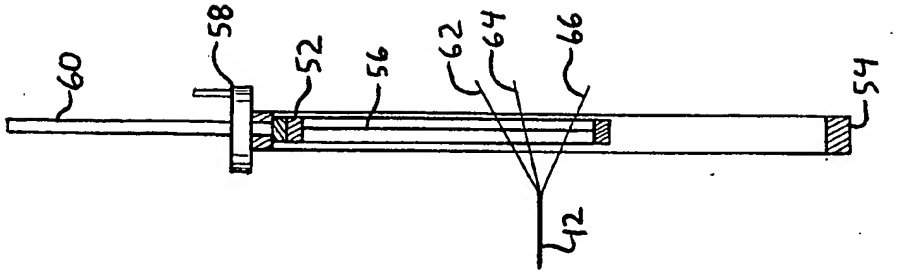

FIG. 4c

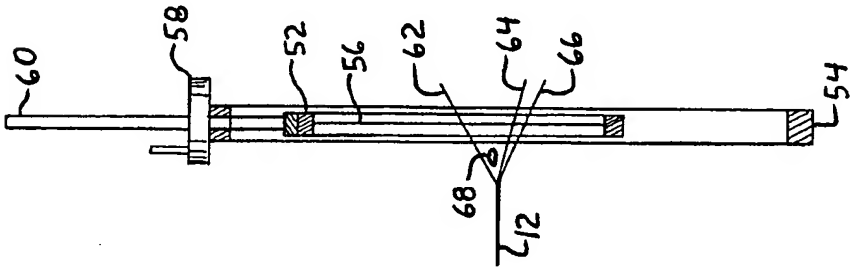

FIG. 4b

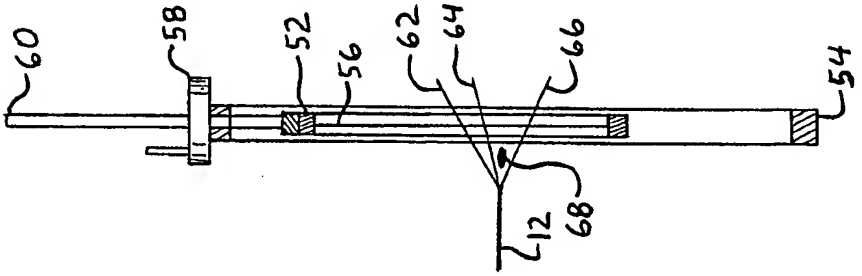

FIG. 4a

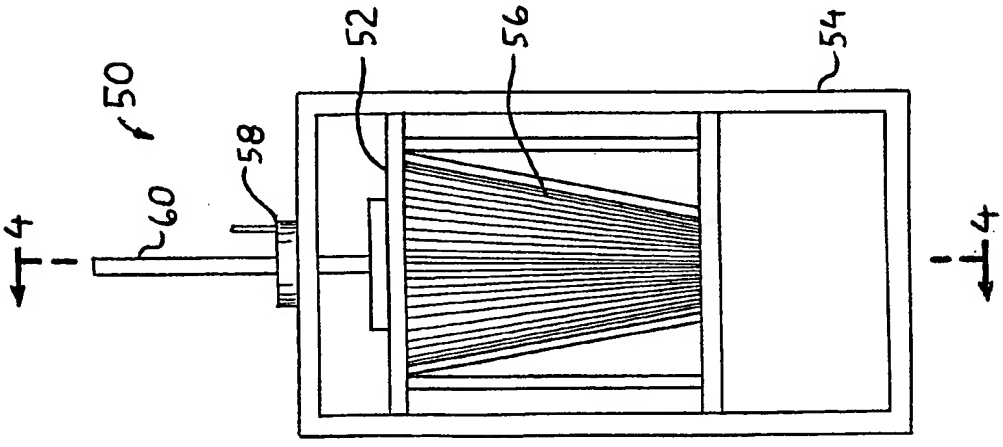

FIG. 3

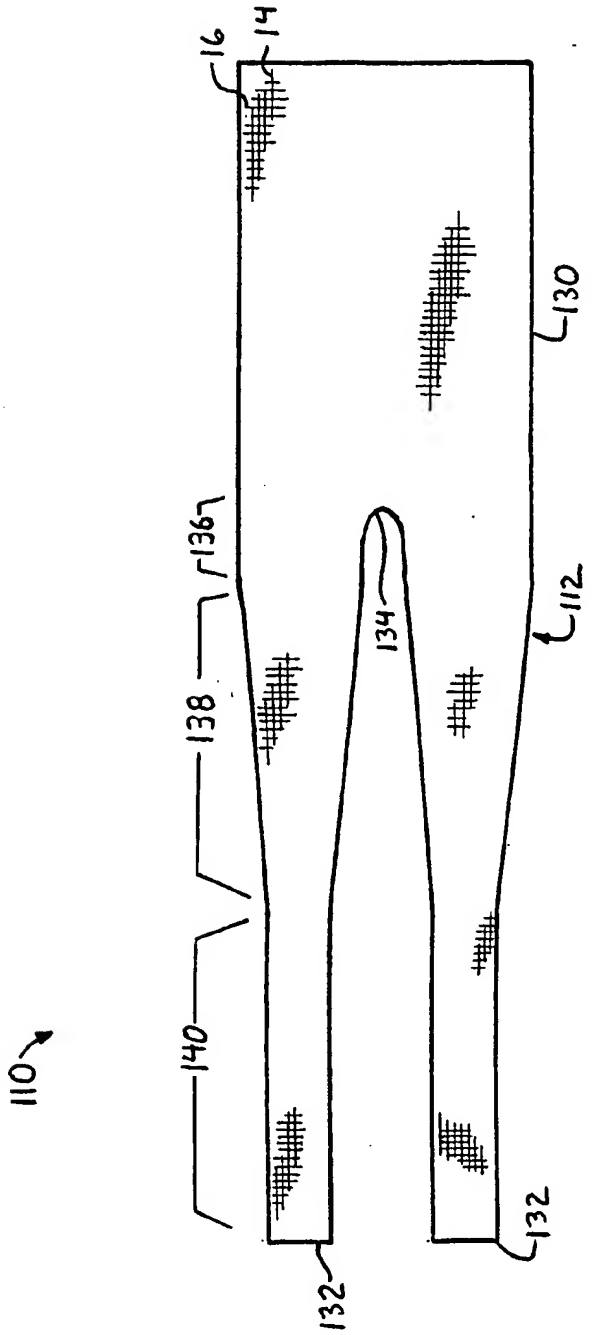

FIG. 5

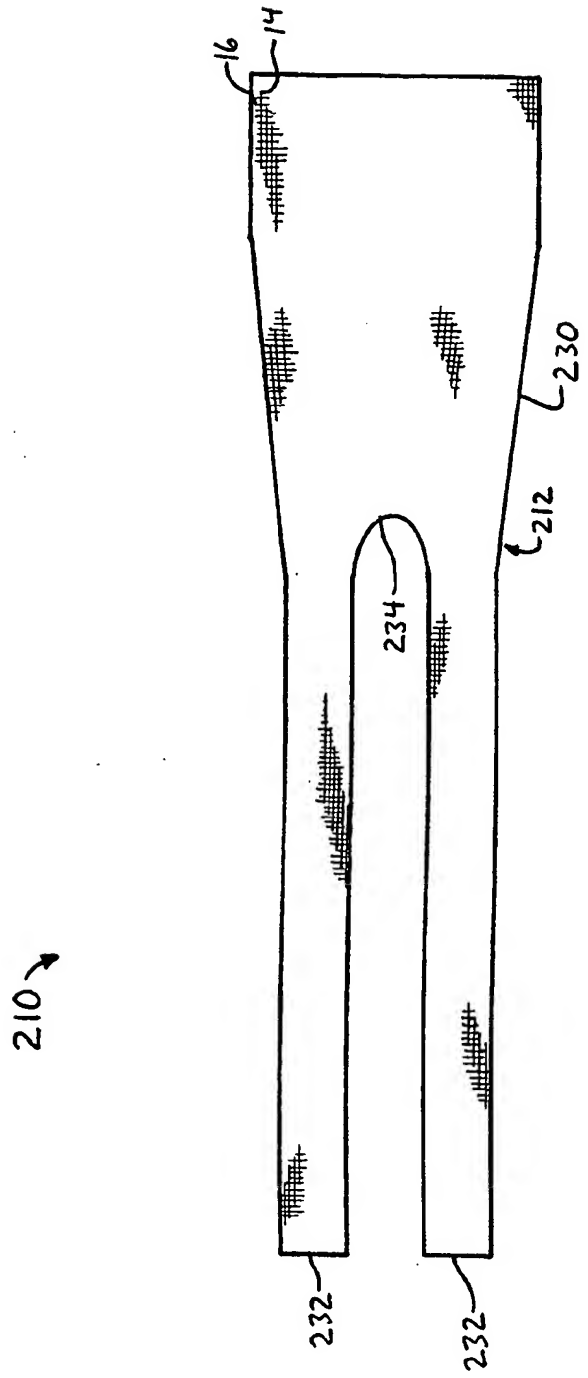

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/01868

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :623/1, 11, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,800,514 A (NUNEZ et al.) 09 September 1998, entire document, and Figs. 1-27.	1-40
Y	US 5,653,747 A (DEREUME) 05 August 1997, cols. 1-8.	28-40
Y	US 4,340,091 A (SKELTON et al.) 20 July 1982, cols. 1-13.	28-40
Y	US 5,653,746 A (SCHMITT) 05 August 1997, cols. 1-8.	1-40
Y	US 3,108,357 A (LIEBIG) 29 October 1963, cols. 1-9.	1-40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 23 MARCH 1999	Date of mailing of the international search report 20 APR 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SUZETTE JACKSON Telephone No. (703) 308-6516

Form PCT/ISA/210 (second sheet)(July 1992)*